



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Bioequivalence Recommendations for Budesonide Extended-Release Tablets; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Budesonide Extended-Release Tablets.” The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for budesonide extended-release tablets.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1615, Silver Spring, MD 20993-0002, 240-402-7290.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for budesonide extended-release tablets.

New drug application 203634 for UCERIS (budesonide) extended-release tablets, 9 milligrams (mg), was initially approved by FDA in January 2013. FDA is now issuing a draft guidance for industry on BE recommendations for generic budesonide extended-release tablets.

In February 2013, Santarus, Inc., submitted a citizen petition requesting that FDA: (1) Issue an individual BE guidance for budesonide extended-release tablets and (2) refrain from approving any ANDA that identifies UCERIS (budesonide) extended-release tablets as the reference listed drug unless the generic product is shown to be bioequivalent based on appropriate data from a clinical efficacy endpoint study, comparative pharmacokinetic testing, in vitro dissolution testing, and pharmacoscintigraphy studies (Docket No. FDA 2013-P-0127). FDA reviewed the issues raised in the petition and is responding to the petition today in a letter that will be included in the citizen petition docket.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for budesonide extended-release tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

or <http://www.regulations.gov>.

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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